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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0303; FRL-9927-75]

Mesotrione; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mesotrione in or on almond, hulls, fruit, citrus, group 10-10; fruit, pome, group 11-10; fruit, stone, group 12-12; and nut, tree, group 14-12. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0303, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0303 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0303, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 2, 2014 (79 FR 44729) (FRL-9911-67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8240) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180.571 be amended by establishing tolerances for residues of the herbicide, mesotrione, in or on citrus fruit, crop group 10-10 at 0.01 parts per million (ppm); pome fruit, crop group 11-10 at 0.01 ppm; stone fruit, crop group 12-12 at 0.01 ppm; tree nuts, crop group 14-12 at 0.01 ppm; and almond hulls at 0.015 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received in response to the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerance for residues of mesotrione in or on fruit, citrus, group 10-10 at 0.01 ppm; fruit, pome, group 11-10 at 0.01 ppm; fruit, stone, group 12-12 at 0.01 ppm; nut, tree, group 14-12 at 0.01 ppm; and almond, hulls at 0.02 ppm. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance

and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for mesotrione including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mesotrione follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In subchronic and chronic oral studies in the rat, mouse, and dog, mesotrione produced ocular (ocular discharge and corneal abnormalities and lesions), kidney (increased organ weights), and liver effects (increased organ weights and hepatocyte fat vacuolation), which are consistent with the mammalian toxicity profile for hydroxyphenylpyruvate dioxygenase (HPPD) inhibitors caused by high tyrosine levels in the blood. Body-weight decrements and decreased food consumption were also noted in mice and rats in multiple studies. Even though the rat was found to be the most sensitive species for these effects, the mouse was identified as a more appropriate model for assessing human risk due to similar activity in mice and humans of an enzyme involved in tyrosine catabolism. There was evidence of increased quantitative susceptibility of rats and mice in the developmental and reproduction toxicity studies. Offspring effects in the developmental toxicity studies were evidenced by delayed ossification and

ancillary ribs and vertebrae at doses below or in the absence of maternal toxicity in both species. In the reproduction toxicity studies, tyrosinemia and ocular discharge were observed in offspring at doses below those for parental toxicity, which was evidenced by increased organ weights (liver in the rat and kidney in the mouse) and tyrosinemia.

Mesotrione was classified as having low acute toxicity via the oral, dermal, and inhalation routes (Toxicity Categories III or IV). It is classified as a mild eye irritant, but it is not a dermal sensitizer or dermal irritant.

There was no evidence of neurotoxicity, mutagenicity, carcinogenic potential, or immunotoxicity in relevant studies. Specific information on the studies received and the nature of the adverse effects caused by mesotrione as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document titled, "Mesotrione. Human Health Risk Assessment in Support of the Section 3 Request for Use of Mesotrione on Pome Fruit, Stone Fruit, Citrus, and Tree Nuts", on page 26 - 29 in docket ID number EPA-HQ-OPP-2014-0303.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a

population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for mesotrione used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for mesotrione for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	Not applicable	Not applicable	No adverse effects attributable to a single dose were observed. As a result, no hazard was identified and an endpoint was not selected.
Chronic dietary (all populations)	LOAEL = 2.1 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF/ $UF_L = 3x$	Chronic RfD = 0.007 mg/kg/day cPAD = 0.007 mg/kg/day	Reproduction study (mouse) LOAEL = 2.1 / 2.4 mg/kg/day (M / F) based on tyrosinemia and ocular discharge. NOAEL not established.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6	LOAEL = 2.1 mg/kg/day $UF_A = 10x$	LOC for MOE = 300	Reproduction study (mouse) LOAEL = 2.1 / 2.4 mg/kg/day (M / F) based

months)	UF _H = 10x FQPA SF/ UF _L = 3x		on tyrosinemia and ocular discharge. NOAEL not established.
Dermal short-term (1 to 30 days), intermediate-term (1 to six months), and long-term (> 6 months)	LOAEL = 2.1 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF/ UF _L = 3x	LOC for MOE = 300	Reproduction study (mouse) LOAEL = 2.1 / 2.4 mg/kg/day (M / F) based on tyrosinemia and ocular discharge. NOAEL not established.
Inhalation short-term (1 to 30 days), intermediate-term (1 to 6 months), and long-term (> 6 months)	LOAEL = 2.1 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF/ UF _L = 3x	LOC for MOE = 300	Reproduction study (mouse) LOAEL = 2.1 / 2.4 mg/kg/day (M / F) based on tyrosinemia and ocular discharge. NOAEL not established.
Cancer (oral, dermal, inhalation)	Classified as “not likely to be carcinogenic to humans” based upon lack of evidence of carcinogenicity in rats and mice.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to mesotrione, EPA considered exposure under the petitioned-for tolerances as well as all existing mesotrione tolerances in 40 CFR 180.571. EPA assessed dietary exposures from mesotrione in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for mesotrione; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America 2003 – 2008. The chronic analysis assumed 100% crop treated (CT), Dietary Exposure Evaluation Model (DEEM 7.81) default processing factors, and tolerance-level residues for all foods. Drinking water was incorporated directly into the dietary assessment using the groundwater concentration and the PRZM-GW model. The chronic dietary risk assessment shows that the chronic dietary risk estimates are not of concern (i.e., <100% chronic population-adjusted dose (cPAD)). The chronic dietary risk estimate for the highest exposed population subgroup, all infants (<1 year old), is 17% of the cPAD.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that mesotrione does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for mesotrione. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for mesotrione in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mesotrione. Further information regarding EPA drinking water

models used in pesticide exposure assessment can be found at

<http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) for surface water and with Screening Concentration in Ground Water (SCI-GROW) and Pesticide Root Zone Model Ground Water (PRZM GW) for ground water, the estimated drinking water concentrations (EDWCs) of mesotrione for chronic exposures for non-cancer assessments are estimated to be 5.1 ppb (1 – 10 year average) and 2.2 (30-year average) for surface water and 18.4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For chronic dietary risk assessment, the water concentration of value 18.4 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Mesotrione is currently registered for the following uses that could result in residential exposures: golf course turf, home lawns, and recreational turf. Both liquid and granular formulations are registered, resulting in potential residential handler (dermal and inhalation) and post-application (dermal and incidental oral) exposures. Residential handler (dermal plus inhalation) exposures were assessed for adults using various handheld equipment. Post-application dermal exposure was assessed for adults, as well as children 11 to <16 years old, children 6 to <11 years old, and children 1 to <2 years old performing various activities on turf. For children 1 to <2 years old, incidental oral (hand-to-mouth) post-application exposure was also assessed. These uses were assessed using the revised 2012 Residential Standard Operating

Procedures. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

There are marked differences among species in the ocular toxicity associated with inhibition of HPPD. Ocular effects following treatment with HPPD inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. One explanation for this species-specific response in ocular opacity may be related to species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves the liver enzyme TAT. In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats.

HPPD inhibitors (e.g., nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient's lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants, children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This observation indicates that an HPPD inhibitor in it and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposures to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. The Agency continues to study the complex relationships between elevated tyrosine levels and biological effects in various species. In the future, assessments of HPPD-inhibiting herbicides may consider more appropriate models and cross species extrapolation methods. Therefore, EPA has not conducted cumulative risk assessment with other HPPD inhibitors.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or

uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was evidence of increased quantitative susceptibility of rats and mice in the developmental and reproduction toxicity studies. Offspring effects in the developmental toxicity studies were evidenced by delayed ossification and ancillary ribs and vertebrae at doses below or in the absence of maternal toxicity in both species. In the reproduction toxicity studies, tyrosinemia and ocular discharge were observed in offspring at doses below those for parental toxicity, which was evidenced by increased organ weights (liver in the rat and kidney in the mouse) and tyrosinemia.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3x for use of a LOAEL from the reproduction toxicity study. That decision is based on the following findings:

- i. The toxicity database for mesotrione is adequate for FQPA assessment.
- ii. There is no indication that mesotrione is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. The ocular discharge seen in the reproduction toxicity study in mice provided a highly conservative endpoint. The LOAEL for this study is currently the lowest dose tested. The incidence of ocular discharge lacked a clear dose response, but an effect was evident at the highest dose tested indicating that the choice of LOAEL in this study may also be conservative.
- iv. There is low concern for susceptibility seen in the developmental and reproduction toxicity studies because the doses and endpoints selected are protective of effects seen in these studies. The doses and endpoints are also protective of developmental effects observed in the rat and rabbit developmental toxicity studies.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to mesotrione in drinking water. The residential exposure assessments are based upon the Residential SOPs, which are based upon reasonable worst-case assumptions. These assessments will not underestimate the exposure and risks posed by mesotrione.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, mesotrione is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to mesotrione from food and water will utilize 17% of the cPAD for infants (< 1 year old) the population group receiving the greatest exposure. Chronic aggregate risk consists only of food and water and does not include residential post-application exposure. Chronic residential exposure is not expected based on the residential use pattern of mesotrione.

3. *Short- and intermediate term risk.* The short-and intermediate-term toxicological PODs for mesotrione are the same for each route of exposure. Therefore, for residential exposure scenarios, only short-term exposures were assessed, and are considered to be protective of intermediate-term exposure and risk.

Short-and intermediate-term aggregate risk is made up of dietary and non-dietary sources of exposure. Since mesotrione has residential uses on turf, including golf courses, commercial, and residential sites, handler and post-application residential exposure is expected. Short- and intermediate-term aggregate risk is made up of average dietary exposures from food and drinking water sources, dermal, inhalation and oral (children only) residential exposures.

Dietary (food + drinking water) exposure estimates are based on a conservative, unrefined chronic dietary exposure assessment. Residential exposure estimates are conservative estimates due to the standard assumptions that were built into the calculations. For adults, dermal plus inhalation exposures from handler activities were factored into the aggregate risk calculations. For children (6 to <11 years old) and children (11 to <16 years old, post-application dermal exposure from activities on treated turf were factored into the aggregate risk calculations. For children (1 to <2 years old), both dermal and incidental oral exposures were factored into the short-and intermediate-term aggregate risk calculations as incidental oral exposure is possible for this population. All short-and intermediate-term aggregate MOEs are not of concern (children 1 to <2 years, MOE = 1,400; children 6 to <11 years, MOE = 4,500; children 11 to <16 years, MOE = 5,800; and adults, MOE = 3,200).

4. *Aggregate cancer risk for U.S. population.* An aggregate cancer risk was not calculated because mesotrione was classified as “not likely to be carcinogenic to humans”.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to mesotrione residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography method with fluorescence detection) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for mesotrione.

C. Response to Comments

On September 2, 2014, EPA published a notice of filing in the **Federal Register** and two comments were received. The commenters noted that pesticides and mesotrione pose a risk to pollinators and human health. The Agency has determined that mesotrione poses no acute contact risk to adult honey bees and there are no risk estimates of concern for human health.

D. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance commodity definition for citrus, pome fruit, stone fruit, and tree nuts are being revised to conform with EPA preferred terms. In addition, based on the method LOQ of 0.01 ppm, EPA is revising the petitioned-for tolerance in/on almond hull of 0.02 ppm rather than 0.015 ppm.

V. Conclusion

Therefore, tolerances are established for residues mesotrione in or on almond, hulls at 0.02 ppm; fruit, citrus, group 10-10 at 0.01 ppm; fruit, pome, group 11-10 at 0.01 ppm; fruit, stone, group 12-12 at 0.01 ppm; and nut, tree, group 14-12 at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive

Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 18, 2015.

Daniel J. Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.571, add in alphabetical order entries for “Almond, hulls”, “Fruit, citrus, group 10-10”, “Fruit, pome, group 11-10”, “Fruit, stone, group 12-12”, and “Nut, tree, group 14-12” to the table in paragraph (a) to read as follows:

§ 180.571 Mesotrione; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	0.02
* * *	
Fruit, citrus, group 10-10	0.01
Fruit, pome, group 11-10	0.01
Fruit, stone, group 12-12	0.01
* * *	
Nut, tree, group 14-12	0.01
* * *	

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